



DESIGNATION OF YELLOW FEVER VACCINATION CENTRES

Information Pack

(January 2012)

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INFORMATION PACK

Foreword

This Information Pack has been prepared by the Travel and International Health Team of Health Protection Scotland (HPS). It sets out the conditions of registration for Yellow Fever Vaccination Centres (YFVCs) in Scotland and provides practical information for those planning to become or that already are YFVCs.

The pack is based on an original document formulated by the National Travel Health Network and Centre (NaTHNaC) upon assuming responsibility for the YFVC's in England, and has been adapted to indicate the specific requirements for YFVC's in Scotland.

Further information on yellow fever and on other health risks overseas can be found on the TRAVAX[®] website at www.travax.nhs.uk. A password is required to access the website but registration is free within the NHS in Scotland. There is a nominal charge for use outwith the NHS. Please enquire on-line.

Health Protection Scotland Contact Details:

The Travel and International Health Team (Yellow Fever)
NHS National Services Scotland
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

www.hps.scot.nhs.uk

Administrative enquiries:

Telephone – 0141 300 1948

Email – nss.hpsyellowfever@nhs.net

Clinical enquiries:

TRAVAX[®] Telephone Helpline: 0141 300 1130

This service is available between the hours of 2.00pm - 4.00pm, Monday and Wednesday, 9.30am - 11.30am on Friday (excluding Public Holidays).

This service is for Healthcare Professionals only.

Enquiries from the General Public:

YFVCs should direct travellers to www.fitfortravel.nhs.uk the public website provided by HPS, which gives travel health advice consistent with that on TRAVAX[®]

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1.0 Introduction

The International Health Regulations (IHR) adopted by the World Health Organization (WHO) in 1969 were formulated to help prevent the international spread of disease, and in the context of international travel, to do so with the minimum of inconvenience to the passenger. The Regulations were designed primarily as a public health measure for the receiving country rather than for the protection of the individual.

The World Health Assembly approved the revised edition of the IHR in May, 2005. As stated in the previous version of the IHR, yellow fever is currently the only disease for which an International Certificate of Vaccination or Prophylaxis may be required for entry into a country. Yellow fever vaccine can only be administered at centres that are designated by the national health administration; for Scotland this was the Scottish Executive Health Department until Health Protection Scotland (HPS) assumed this responsibility in December 2006. The requirement for designating centres is to ensure the “quality and safety of the procedures and materials employed”¹. The legislative authority for HPS to do this on behalf of the Scottish Government falls under section 10 of the National Health Service (Scotland) Act 1978 and specifically the National Health Service (Functions of the Common Services Agency) (Scotland) Amendment, (No 2) Order 2006 SSI/2006/603².

In view of the requirement for NHS organisations to improve and assure quality through a system of clinical governance and risk management³, HPS require standards of practice within designated YFVC’s in Scotland. Independent clinics are expected to maintain standards at least equal to those in the NHS, although legislative arrangements governing the regulation of these private services are not yet in place for Scotland^{4,5}. The Medicines and Healthcare Products Regulatory Agency (MHRA) website has information about the use of patient group directions (PGD’s) within services in the private sector, with particular reference to “Arrangements for Scotland”⁶.

Advice on the prevention of yellow fever is essential for all travellers visiting yellow fever endemic areas. These travellers may also be at risk from other vaccine and non-vaccine preventable diseases, including malaria. The YFVC will be expected to ensure that the traveller is aware of these risks and other issues relative to travel and must either advise accordingly or direct the traveller to a source of such advice. YFVC’s are encouraged to register with and use TRAVAX[®], a web-based resource detailing travel health risks including yellow fever and malaria. It is a source of national guidance for health professionals advising travellers, developed and managed by the THT of HPS. Registration is free within the NHS in Scotland. There is a nominal charge for use out-with NHS Scotland. Register online at www.travax.nhs.uk. In addition, YFVCs should encourage travellers to look at www.fitfortravel.nhs.uk the public web-site provided by HPS, which gives travel health advice consistent with that on TRAVAX[®].

This Information Pack provides the information required for application to become a designated YFVC. The IHR are explained, together with information on completing an International Certificate of Vaccination or Prophylaxis, requirements for record keeping, storage and disposal of vaccine, and suggested procedure should there be an interruption of the cold chain. Guidelines for the administration of yellow fever vaccine, resuscitation and anaphylaxis and training programmes for YFVCs are identified.

1. Revision of International Health Regulations. WHA 58.3. Fifty-eighth World Health Assembly. 23 May 2005. Annex 6 and 7. Also see Chapter 1 Arrival and Departure. Available at <http://www.who.int/csr/ihr/en/>

2. National Health Service Amendment Order http://www.oqps.gov.uk/legislation/ssi/ssi2006/ssi_20060603_en_1

3. NHS Quality Improvement Scotland <http://www.nhshealthquality.org/nhsqis/43.140.140.html>

4. Scottish Commission for the Regulation of Care <http://www.carecommission.com>

5. Scottish Executive Health Department <http://www.scotland.gov.uk/Topics/Health/care/17652/17963>

6. MHRA http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON009687

2.0 The International Health Regulations and International Certificates of Vaccination or Prophylaxis

2.1 International Health Regulations

2.2 International Certificate of Vaccination or Prophylaxis

2.3 Reissue of International Certificate of Vaccination or Prophylaxis against Yellow Fever

2.4 Supply of International Certificate of Vaccination or Prophylaxis

2.1 International Health Regulations and Yellow Fever

The International Health Regulations¹ of the WHO, are formulated in part to reduce the risk of the spread of yellow fever. The regulations aim to restrict movement between countries of individuals who are considered as having been exposed to yellow fever virus and who may be capable of spreading the disease. The IHR are thus designed primarily as a public health measure for the receiving country rather than for protection of the individual.

A proportion of mandatory vaccination against yellow fever is carried out with the aim of preventing yellow fever virus from being imported into vulnerable countries. These are countries where yellow fever does not occur but where the mosquito vector and non-human primate hosts are present, and therefore, conditions are conducive for the introduction of yellow fever. If the virus was imported, this could lead to establishment of infection in mosquitoes and primates, with a consequent risk to the local population. In these cases, vaccination may be an entry requirement for all travellers (including, occasionally, airport transit) arriving from countries where there is a risk of yellow fever transmission. In some circumstances, failure to provide a valid certificate to the port health authorities could result in a traveller being quarantined, immunised or denied entry.

Information on country requirements for yellow fever is published annually by the WHO in International Travel and Health⁷.

Note: The absence of a requirement for vaccination (refer to WHO International Travel and Health or TRAVAX[®] country-specific pages) does not imply that there is no risk of yellow fever in the country. Yellow fever immunisation may be recommended for the protection of the individual traveller. Yellow fever vaccinators should have access to current information on disease risks and outbreaks (see section 12 on Sources of Information).

If yellow fever vaccination is contraindicated for medical reasons (including infants < 9 months of age), this should be stated in a medical exemption letter, in English (or French). The traveller should also be informed of the risks associated with non-vaccination. The health authorities at the destination should take this letter into account on arrival¹. (see Appendix 4).

7. International Travel and Health, World Health Organisation 2011 <http://www.who.int/ith/en/>

2.2 International Certificate of Vaccination or Prophylaxis

Persons undergoing yellow fever vaccination under IHR shall be provided with an International Certificate of Vaccination or Prophylaxis; certificates conforming to the IHR model can be obtained from HPS (see section 2.4 and example below). It should be noted that no departure from this certificate is permitted. Any amendment of the certificate or erasure or failure to complete any part may render the certificate invalid (to include completion of the details with regard to the manufacturer and batch number of the vaccine given). The International Certificate of Vaccination or Prophylaxis is valid only if the vaccine used has been approved by WHO, and if the vaccinating centre has been designated by the appropriate health administration.

Example of international certificate of vaccination or prophylaxis⁷



This is to certify that (name)....., date of birth.....

sex....., nationality....., national identification

document if applicable....., whose signature follows

.....
has on the date indicated been vaccinated or received prophylaxis against:

(name of disease or condition).....

Vaccine or prophylaxis	Date	Signature and professional status supervising clinician	Manufacturer and batch no. of vaccine or prophylaxis	Certificate valid From.... Until....	Official stamp of administering centre
1. Yellow Fever	10 August 2007	 MRCGP	Sanofi Pasteur MSD Batch:Z59225	20 August 2007 19 August 2017	
2.					

The International Certificate of Vaccination or Prophylaxis is valid for a period of 10 years, beginning 10 days after the date of vaccination, or in the event of revaccination, for a 10-year period from the date of the revaccination.

The International Certificate is an individual certificate and cannot be used for more than one person. A separate certificate should be issued for children. A parent or guardian should sign a certificate that is issued to a child who is unable to write. If that parent or guardian is either illiterate or otherwise unable to write, it will be permissible to indicate a signature by that person's mark together with the indication of another person that the mark made is the mark of the person concerned.

The certificate must be printed in English and French and completed in English or French; an additional language may be added. In the UK these certificates are preprinted (see section 2.4).

Either the registered medical practitioner responsible for the YFVC or other authorised health worker must sign the certificate. Any nurse or pharmacist employed at a designated YFVC who carries out vaccination under the direct supervision of a medical practitioner is authorised to sign an International Certificate of Vaccination or Prophylaxis. The certificate must also bear the official stamp of the administering centre (see Appendix 1b) however this will not be accepted as a substitute for the signature such that both are required.

The date must be recorded as follows: the day placed first in numerals; the month should appear second in letters, the year should come last in numerals, for example: 10 August 2007. Individuals should store the certificate in a safe place, usually with their passport, and be encouraged to make a photocopy that is kept separately, and would be of assistance should re-issue become necessary.

2.3 Re-issue of International Certificates of Vaccination or Prophylaxis against Yellow Fever

In the case of a lost certificate, the original administering YFVC should ideally re-issue it. A re-issued certificate need not be signed by the original vaccinator and can be signed instead by a person authorised to sign at the time of reissue. However, in these circumstances, the name of the original vaccinator should be noted in the records where possible. The date on the certificate should be the date of the original vaccination. If the original administering YFVC is no longer a designated centre, or the patient is unable to attend the original administering YFVC, any designated YFVC may reissue a certificate. In order to do this they must be satisfied that the individual has been vaccinated and that sufficient information is available to complete the certificate, i.e. date of vaccination, manufacturer and batch number of vaccine.

If the patient has lost their International Certificate of Vaccination or Prophylaxis against Yellow Fever, and the records of the original vaccination are also lost, the patient may have to be revaccinated in order to assure that they are protected against yellow fever.

In every case it is important that the re-issuing practitioner is satisfied that the patient is adequately protected against yellow fever, and when there is doubt about that protection, a repeat vaccination should be performed. Individual advice should be sought if this situation occurs within 4 weeks of the original vaccination.

When there is a name change since the issue of the original certificate, for example marriage or divorce, the name change should be verified by checking passport details or by inspection of appropriate official documentation relating to the name change.

2.4 Supply of International Certificates of Vaccination or Prophylaxis

Certificates conforming to International Health Regulations come packaged along with the yellow fever vaccine. Sanofi Pasteur MSD, who manufacture and distribute Stamaril® yellow fever vaccine facilitate this arrangement.

HPS holds a small stock of certificates should centres require a few extra copies above those supplied with the vaccine. These can be obtained via existing routes, either by phoning HPS (0141 300 1137) or by ordering on-line (www.hps.scot.nhs.uk/yellowfever/order.aspx).

3.0 Designation as a Yellow Fever Vaccination Centre and Application Procedure

- 3.1 Conditions of designation
- 3.2 Application procedure
- 3.3 Yellow Fever Vaccination Centre Identification Number
- 3.4 Withdrawal of designation of YFVC status

3.1 Conditions of designation

Since yellow fever vaccine can only be administered at centres designated by State Parties¹, branch surgeries or additional surgeries that have a different geographical location are required to register separately as a YFVC.

It is a condition of designation that the registered medical practitioner who is responsible for the centre confirms that:

- a) The centre will administer only yellow fever vaccines approved by the WHO.
 - For a list of approved yellow fever vaccines see Appendix 2 of this information pack.
- b) All yellow fever vaccinations carried out at the centre will be performed by the responsible medical practitioner, or by a suitably qualified person (doctor, nurse, pharmacist) acting under his/her direction and control.
 - For more information regarding immunisation by nurses and pharmacists refer to Immunisation against infectious disease 2006, Chapter 5⁸.
- c) Facilities for administering and storing vaccines will be of an acceptable standard
 - Refer to sections 4 -10.
- d) Appropriate policies for safe administration of yellow fever vaccine will be in place, and all staff involved in administration of vaccine will be appropriately trained. Such knowledge and training must include:
 - risk assessment for travel
 - requirements for vaccination as a condition for entry to a country
 - the safe administration of yellow fever vaccine
 - yellow fever disease prevention measures
 - potential vaccine-associated adverse events.

The YFVC will be expected to ensure that the traveller is aware of these risks and other issues relative to travel and must either advise accordingly or direct the traveller to a source of such advice.

- e) The centre will comply with staff training as required by HPS.
- f) The centre will keep appropriate records of all vaccinations administered. Records will be maintained for 10 years following each yellow fever vaccination. In the event of closure of a YFVC, records pertaining to Yellow Fever Vaccination must be archived according to local guidelines.

8. Department of Health. Immunisation against infectious diseases, 2006 available at:
http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254

- g) International Certificates of Vaccination or Prophylaxis against yellow fever will be completed and signed by the vaccinator in accordance with IHR
 - Refer to section 2.2 regarding authorisation for nurses and pharmacists to sign the International Certificate of Vaccination or Prophylaxis.
- h) Vaccine associated adverse events will be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) via the yellow card system
 - Refer to Appendix 6.
- i) Annual returns of vaccine utilisation will be returned to HPS electronically or by post on the Annual Return form provided at Appendix 7. This is to allow statistical and research analysis; returns from individual clinics will not be publicly available.
- j) HPS will be notified immediately of any changes, which may affect the centre's registration status.
 - In particular, a new registered medical practitioner in charge of the clinic will be required to submit a new declaration
 - Should the responsible registered medical practitioner move to a new site, they must re-apply for designation for the new site.
- k) If requested, HPS will be given access to the centre or receive copies of YFVC records to ensure that the centre is complying with the conditions of registration
- l) The centre's status as a designated YFVC will be reviewed biennially.

3.2 Application procedure

A registration fee of £65.00 (+ vat where appropriate) has been introduced for all YFVCs in Scotland. The fee will be due **every two years** at the time of re-registration.

This fee includes:

- registration for two years
- access to programme of re-training
- supply of the International Certificate of Vaccination or Prophylaxis (yellow fever certificate)

Newly applying centres wishing to become registered will need to attend training **before** their application can be fully processed. (see Section 10.0)

The registered medical practitioner needs to complete an application form and agree and sign the Conditions of Registration for Designation (see Appendix 1 and 1a).

Completed forms should be returned to the following address:

The Travel and International Health Team (Yellow Fever)
NHS National Services Scotland
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

Applications will be reviewed to assess whether the centre complies with the necessary conditions of designation. Centres must be prepared to give access to representatives of HPS who may visit, or to send copies of required documentation, to ensure these conditions are being met.

An application checklist is included at Appendix 1b to help with the process of applying.

3.3 Yellow Fever Vaccination Centre Identification Number

Once a centre has been confirmed as designated, HPS will issue each centre with a unique identification number. This should be quoted in all correspondence with HPS and is the number which should be included on the official stamp used by the centre for International Certificates of Vaccination or Prophylaxis (see Appendix 1c).

3.4 Withdrawal of Designation of Yellow Fever Vaccination Centre status

YFVCs that do not conform to the conditions of registration for designation will be removed from the central register of YFVCs and will have their status as a registered YFVC revoked. The process for de-designation of centres can be found at Appendix 9.

4.0 Administration of Vaccines Including Yellow Fever Vaccine

Immunisation is an important method of preventing infectious disease. Successful immunisation will depend on a number of factors, including the use of a safe and effective vaccine, proper vaccine storage conditions, obtaining consent and using the correct injection technique into the correct site. Those administering the vaccine must be familiar with the Summary of Product Characteristics (SPC) of this live attenuated vaccine including contraindications and potential adverse events.

General information relating to immunisation procedure, technique and consent is documented in Immunisation against infectious disease 2006⁸ (The Green Book).

Sources of information relating to the administration of yellow fever vaccine include the SPC for individual vaccines, the medical information department of the relevant vaccine manufacturer and in the yellow fever disease information record on TRAVAX[®] (www.travax.nhs.uk)

5.0 Requirements for Record Keeping

Records of all yellow fever vaccinations must be maintained. Where the person to be vaccinated is a registered patient of the YFVC centre, written record of yellow fever vaccination should be made in the patient's medical record. Persons attending the centre who are **not** registered patients at that centre should have a personal record constructed that should be retained by the centre.

Record of vaccination should include:

- date of vaccination
- vaccine proprietary name and manufacturer, batch number and expiry date of the vaccine
- name and status of the vaccinator (in block capitals where the record is hand written)
- special instructions or advice given to the person vaccinated, or if a child, to the person responsible for the child
- consent of the person to be vaccinated, inclusive of the risks and warnings given to the person with regard to the vaccination. Further information on consent can be obtained from Immunisation against infectious disease 2006⁸ (The Green Book), Chapter 2

- other remarks as appropriate.

A **separate record** (see Appendix 8 for example) should be made of **all** yellow fever vaccinations given at the centre. This record should include:

- patient name (and identification number where relevant)
- date of vaccination
- vaccine proprietary name and manufacturer, batch number and expiry date of the vaccine
- name and status of the vaccinator (in block capitals where record is hand written)
- special instructions or advice given to the person vaccinated, or if a child, to the person responsible for the child
- other remarks as appropriate.

In addition, where a letter of exemption has been issued, it is recommended that this is recorded, including the reason for the exemption and the date it is to expire.

Records of yellow fever vaccination should be kept for a period of at least 10 years from the date of the most recent vaccination. Records of children who have been vaccinated are to be retained until their 25th birthday⁹. If the centre ceases to be a designated YFVC, it must make adequate arrangements for the record to be kept either by the centre or by transferring it to another centre. In either case HPS should be informed of the change and of the arrangements made for transfer, storage and access to the patient records.

Guidance on the retention and destruction of personal health records was last issued to organisations within NHS Scotland in 1993 in NHSMEL (1993) 152⁹. This guidance is currently under review, with the aim of providing clear instructions to organisations within NHS Scotland on the periods of time that they must keep personal health records, whether stored on paper, computers, or other form.

6.0 Storage of Yellow Fever Vaccine

A suitably trained person should be nominated for each YFVC to be responsible for the safe storage of the vaccine. There should be a designated deputy to cover in times of absence. Yellow fever vaccine should be transported and stored at +2°C to +8°C. Manufacturers' recommendations on storage must be observed. Should any vaccines be either transported and/or stored out-with this range, then such vaccine should not be used until advice has been sought from the vaccine manufacturer and/or community pharmacist (see Section 8). To ensure good practice, vaccine must be stored in a pharmacy or vaccine refrigerator. Pharmacy or vaccine refrigerators are generally of a higher specification than domestic varieties and are designed for the storage of vaccine products.

Pharmacy or vaccine refrigerators should be:

- capable of measuring minimum and maximum temperatures within the refrigerator cabinet
- fitted with an external digital minimum and maximum memory display
- capable of automatic defrosting
- secured with an integral locking system (which complies with Control of Substances Hazardous to Health (COSHH) regulations)¹⁰.

9. Scottish Executive: Retention and Disposal of Health Records: Consultation on New Guidance to NHS Scotland <http://www.scotland.gov.uk/Publications/2005/09/12141101/11017>

10. Control of Substances Hazardous to Health Regulations 2002. <http://www.hse.gov.uk/index.htm>

The temperature of the refrigerator storage compartment should be recorded at least once daily, at the beginning of each immunisation session⁹. After recording, the refrigerator thermometer(s) should be reset. In addition to any integral temperature monitoring system, an independent maximum and minimum thermometer, located within the refrigerator cabinet, should be used to independently monitor the internal refrigerator temperature. Temperature logs should be available for inspection if required (for example see Appendix 5).

Care should be taken to ensure that the electricity supply to the vaccine refrigerator could not be accidentally interrupted. This can be assisted by using a fused spur (i.e. a switchless socket) or by placing cautionary notices on plugs and sockets (or back up generators where available). All staff should be aware of the procedure to follow should a break in the cold chain occur (see Section 8). Instructions for the use and handling of vaccine products may differ. Reconstituted vaccine must be used within the recommended period, according to manufacturer's instructions, usually within 60 minutes. Information relating to the administration of yellow fever vaccine is contained in the SPC for individual vaccines and is available from the medical information department of the relevant vaccine manufacturer. Procedures followed for storage, distribution and disposal of vaccines should be audited regularly.

7.0 Disposal of Yellow Fever Vaccine^{11,12}

All needles and syringes should be disposed of immediately following use into a puncture resistant sharps container. The container should be to British Standard BS 7320. Needles should not be resheathed. Unused vaccine, spent or partly spent vials should be disposed of safely, preferably by heat inactivation or incineration. Contaminated waste and spillage should be dealt with by heat sterilisation, incineration or chemical disinfection as appropriate. Those providing or handling live vaccines should follow local policy with regards suitable procedures for vaccine disposal.

11. UK Health Departments Guidance for Clinical Healthcare Workers: Protection against Infection with Blood Borne Viruses. Recommendations of the Expert Advisory Group on AIDS and the Advisory Group on Hepatitis. HMSO 1998

12. Guidance on vaccine storage and handling. Health Protection Scotland, 2010, available at <http://www.hps.scot.nhs.uk>

8.0 Interruption of the Cold Chain^{1,3}

Vaccines should be stored according to the manufacturer's instructions. This is normally between +2°C to +8°C. In general, any vaccine that has been exposed to temperatures outside the recommended storage range should not be administered.

In the event of vaccines being stored at temperatures outwith the recommended range the vaccine manufacturer/community pharmacist should be contacted for advice and the following information provided:

- length of time the refrigerator has been off / malfunctioning
- current internal temperature of refrigerator
- minimum and maximum temperature during last 24 hours (temperature records should be made at least daily)
- previous current minimum and maximum temperatures
- type of vaccine product, date of expiry and batch numbers

The following actions should be taken:

- discard any stock as advised by manufacturer / pharmacist (see Section 7)
- return salvageable products (as advised by the manufacturer/pharmacist) to cold chain immediately and use only as directed by the manufacturer

Inform the practice manager who should:

- complete critical incident procedure to allow risk analysis
- check insurance policy covers for loss of stock
- notify patients if revaccination is required.

If an individual is subsequently found to have inadvertently received a vaccine that has been exposed to temperatures outside the recommended storage range, or if the vaccine is found to have passed its expiry date, advice should be sought on an individual basis from the vaccine manufacturer/local community pharmacist or Consultant in Public Health Medicine.

Further advice on vaccine storage can be obtained from Immunisation against infectious disease 2006⁸ (The Green Book), Chapter 3 and the Royal Pharmaceutical Society of Great Britain¹². WHO has also produced a useful reference document on temperature sensitivity of vaccines¹³ which can also be found on TRAVAX[®].

Local Community Pharmacist

Name.....Contact number:.....

13. Galazka A, Milstien J, Zaffran M. Global Programme for Vaccines and Immunization. Thermostability of vaccines. WHO/GPV/98.07. Geneva: World Health Organization; 1998.

9.0 Resuscitation and anaphylaxis

All Healthcare professionals who administer vaccines must be familiar with recognition and treatment of a patient with anaphylaxis. Training must follow local policy in terms of frequency. Preparation must be made for the management of anaphylaxis and other immediate reactions to vaccination. Epinephrine (Adrenaline) and basic life-support equipment must be immediately available whenever a vaccine is administered.

Current UK resuscitation guidelines are provided by the Resuscitation Council¹⁴ on procedure and management of anaphylaxis and should be available within each YFVC.

10.0 Training

As part of the Yellow Fever Vaccination Centre (YFVC) programme being delivered on behalf of the Scottish Government, Health Protection Scotland (HPS) is responsible for the mandatory training requirements for designated YFVC's in Scotland.

Each YFVC is required to have **one** member of staff (doctor, nurse, pharmacist) complete training every two years. It is expected that the staff member who completes the training will cascade information to other relevant staff working in the YFVC.

Newly applying centres wishing to become registered will need to attend training **before** their application can be fully processed.

Further information on training and available dates can be located on the HPS website at www.hps.scot.nhs.uk

It should be reiterated that all those involved in administering travel vaccines, including yellow fever, have some knowledge of travel-associated health risks, including the risk of malaria. YFVCs should ensure that travellers are aware of these risks and be able to advise accordingly or direct the traveller to a source of such advice.

11.0 Assessment and Audit

YFVCs are required to abide by the "Conditions of Registration for Designation" (Appendix 1a). In order to ensure safe, high quality healthcare for patients and users of the YFVC, HPS requires assessment and audit of the YFVC's.

The Assessment and Audit process has as its purpose the provision of sufficient information by the designated YFVC to enable HPS to have confidence in the competency of the centre to remain a designated centre. Oversight of this process is within the remit of the Clinical Governance Committee of HPS and issues will be directed via this route. (www.hps.scot.nhs.uk)

14. Resuscitation Council Guidelines 2011 available at: www.resus.org.uk

12.0 Further Sources of Information on Yellow Fever and Yellow Fever Vaccine

12.1 Description of Disease, Transmission and Epidemiology

WHO at www.who.int/topics/yellow_fever/en/

12.2 Vaccine Requirements

WHO International Travel and Health 2011 (published annually) available at: <http://www.who.int/ith/>

Health Protection Scotland, TRAVAX[®] Country pages: www.travax.nhs.uk

Health Protection Scotland, Fitfortravel[®] Country pages: www.fitfortravel.nhs.uk

12.3 Vaccine Recommendations

Health Protection Scotland, TRAVAX[®] database at: www.travax.nhs.uk

Health Protection Scotland: 0141 300 1130 (2.00–4.00 pm weekdays: for Health Professionals only)

NaTHNaC Advice Line: 0845 602 6712 (9-12 & 2-4.30 pm weekdays: for Health Professionals only)

12.4 Vaccine information

Department of Health; Immunisation against infectious disease 2006 (The Green Book) at: http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/DH_4097254

Sanofi Pasteur MSD: Tel: 01628 773737
www.apmsd.co.uk/indexpro.html

Centers for Disease Control and Prevention: “Yellow Fever Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP)” 2002 MMWR, Recommendations and Reports. November 8, 2002 / 51 (RR17); 1 – 10. at:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5144a1.htm>

CDC at: www.cdc.gov/ncidod/dvbid/yellowfever/index.html

12.5 Outbreaks of yellow fever

WHO outbreak pages at <http://www.who.int/csr/don/en/>

WHO: Disease Outbreak News Information on ‘infected areas’ is published in the Weekly Epidemiological Record on a weekly basis at <http://www.who.int/wer/en/>

Health Protection Scotland, TRAVAX[®] Outbreak Index at: www.travax.nhs.uk

APPLICATION FOR DESIGNATION AS A YELLOW FEVER VACCINATION CENTRE

Title of Centre: _____

Person responsible for centre: _____
(registered medical practitioner)

Address of centre : _____

City/Town: _____

Post code: _____ Health Board Area: _____

Tel number: _____ Fax number: _____

Email: _____ Website address: _____

The centre is:

- a. A health centre or surgery of a registered general medical practitioner
- b. Occupational health department of an organisation
- c. A centre managed by an NHS trust or Health Board
- d. An independent clinic (eg. of a travel company or airline)
- e. Other (please specify): _____

Vaccination will be available to:

- a. Practice patients only
- b. Practice patients and members of the public
- c. Members of the public
- d. Employees only
- e. Other (please specify): _____

Contact details for the centre will automatically be placed on the Health Protection Scotland website.

Please indicate if you do not wish this to happen:

I do not want details of the centre on the HPS website

Please complete form and return to: The Travel and International Health Team (Yellow Fever), NHS National Services Scotland, Health Protection Scotland, 4th Floor, Meridian Court, 5 Cadogan Street, Glasgow G2 6QE

CONDITIONS OF REGISTRATION AS A DESIGNATED YELLOW FEVER VACCINATION CENTRE (YFVC) IN SCOTLAND

The registered medical practitioner responsible for the YFVC must agree to comply with the following Conditions of Registration and sign to this effect below:

1. The centre will administer only yellow fever vaccines approved by the World Health Organization (WHO).
2. All yellow fever vaccinations carried out at the centre will be performed by the responsible medical practitioner, or by a suitably qualified person (doctor, nurse, pharmacist) acting under his/her direction and control.
3. Facilities for administering and storing vaccines will be of an acceptable standard.
4. Appropriate policies for safe administration of yellow fever vaccine will be in place, and all staff involved in administration of vaccine will be appropriately trained.
5. The centre will comply with staff training as required by Health Protection Scotland (HPS).
6. The centre will keep appropriate records of all vaccinations administered.
7. The International Certificate of Vaccination or Prophylaxis will be completed in accordance with WHO International Health Regulations (IHR), bearing a specified YFVC registered stamp and signed by an authorised vaccinator.
8. All vaccine associated adverse events will be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA).
9. Annual returns of vaccine utilisation will be sent to HPS.
10. HPS will be notified immediately of any changes, which may affect the centre's registration status.
11. If requested, HPS will be given access to the centre or receive copies of YFVC records to ensure that the centre is complying with the conditions of registration.
12. The centre's status as a designated YFVC will be reviewed biennially.

I have read and understood the information pack "Designation of Yellow Fever Vaccination Centres". I understand that failure to comply with these Conditions of Registration may result in the centre's designation as a YFVC being withdrawn.

Signature: _____ Date: _____

Full Name (*block capitals*): _____

Qualifications: _____

GMC Registration Number: _____

Please complete form and return to: The Travel and International Health Team (Yellow Fever), NHS National Services Scotland, Health Protection Scotland, 4th Floor, Meridian Court, 5 Cadogan Street, Glasgow G2 6QE

APPLICATION CHECKLIST

Read the Yellow Fever Information Pack

Designation of Yellow Fever Vaccination Centres

Apply to attend yellow fever training day

Complete the Application Form

Complete and sign the Conditions of Registration

This form must be completed and signed by the designated responsible person (a registered medical practitioner). General Medical Council number should be included.

Send completed forms to Travel Health Section (Yellow Fever), HPS

***The Travel and International Health Team (Yellow Fever)
NHS National Services Scotland
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE***

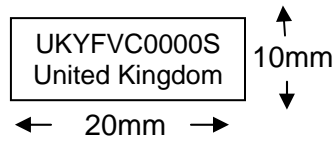
Appendix 1c

Yellow Fever Vaccination Centre Official Stamp

YFVCs are required to use an official stamp on all International Certificates of Vaccination or Prophylaxis against yellow fever. (see Section 3.3). This stamp should include the unique identification number allocated to you by HPS, following designation.

The YFVC stamp is **not** provided by Health Protection Scotland (HPS) but should be ordered by the YFVC. In order to fit the yellow fever certificate (the *International Certificate of Vaccination or Prophylaxis*), **the stamp should measure as close to 20mm by 10mm as possible and contain only your YFVC number and the words “United Kingdom”.**

Example:



We appreciate that there may be difficulties sourcing a stamp of these dimensions. A couple of suppliers are listed below, provided as an example to assist those who are having difficulties sourcing a supplier.

Example of stamp suppliers: (HPS does not endorse these websites)

Ash Rubber Stamp Co. Ltd (stamp available at 20mmX10mm)
www.ashstamp.co.uk

Custom Stamps Online (stamp available at 25mmX12mm)
www.customstampsonline.com

Freephone: 0800 0327296

Rubberstamp Factory (stamp available at 26mmX9mm)
www.stampfactory.co.uk

Appendix 2

Vaccine Suppliers

Yellow fever vaccine (WHO approved) may be obtained from the following:

Stamaril™, available from

Sanofi Pasteur MSD Ltd

Mallards Reach

Bridge Avenue

Maidenhead

Berkshire

SL6 1QP

Tel: 01628 785291

Website: www.apmsd.co.uk/indexpro.html

It is important to note that HPS do not manufacture or supply yellow fever vaccine.

This process is controlled by private sector pharmaceutical companies. Please be aware the shortages in the supply of vaccine have been known to occur. If this occurs, HPS will engage in discussions with vaccine manufacturers, the Scottish Government and other stakeholders. HPS will aim to keep YFVCs informed of the outcome of these discussions. Specific queries about vaccine supply and availability should be directed to suppliers.

Appendix 3

Suppliers of medical refrigerators

Medical refrigerators designed for the storage of vaccines are readily available and come in a variety of sizes to cater for individual requirements. They can be purchased from distributors either through catalogues, by telephone or online.

Examples: (HPS does not endorse these companies)

Vicarey Davidson & Co
Unit 10
30A Cumberland Street
Glasgow
G5 9QJ
Tel: 0141 420 1778
Online: available soon

On call Medical Supplies
Tel: 0845 230 8930
Online: <http://www.oncallmedicalsupplies.com>

Dorset Nursing Supplies
Tel: 01202 425070
Online: <http://www.dorset-nursing.co.uk>

Medisave
Tel: 0800 804 6447
Online: <http://www.medisave.co.uk>

MIC Global (UK)
Tel: 0207 274 2314
Online: <http://www.micglobal.co.uk>

Williams Medical
Tel: 01685 846666
Online: <http://www.wms.co.uk/>

Suppliers of Maximum / Minimum Thermometers

Example:

Williams Medical
Tel: 01685 846666
Online: <http://www.wms.co.uk/>

NB. This list is not exhaustive and does not necessarily represent a recommendation on the part of HPS.

Appendix 4

Example Medical Exemption from the requirement for an International Certificate of Vaccination or Prophylaxis

Where a physician advises that an individual should not be vaccinated on medical grounds, this should be written on headed writing paper. This medical exemption will be taken into consideration by the port health authorities in the destination country. If there is sufficient time, a traveller could request from the High Commission or Embassy of the country or countries to be visited, a letter accepting the exemption. Although this may be helpful on entry, in practice not all embassies are able to guarantee the attitude of individual port health officials or provide written assurances.

Example:

Re: Name _____

DOB _____

Passport number _____

This is to certify that on medical grounds I advise that Yellow Fever vaccine is contraindicated in the above named person and should not be given.

Date _____

Expiry _____

Signed _____

Print name _____

(PRACTICE STAMP)

Appendix 5

Example of Temperature Log Chart

Refrigerator Temperature Record

- Temperatures should be between **2 – 8 C**
- Monitor and record daily
- If temperatures fall outwith the recommended range, report to person in charge for action

DATE	TIME	Current Temp.	Min. Temp.	Max. Temp.	Reset Therm. tick	Checked by Initials	Comments
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
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26							
27							
28							
29							
30							
31							

Appendix 6

Adverse reaction reporting to Medicines and Healthcare Products Regulatory Agency

Adverse events relating to yellow fever vaccine should be reported to the MHRA by one of the following methods:

- The MHRA Website:
http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=285
- Yellow card free posted to: Medicines and Healthcare Products Regulatory Agency, CHM Scotland, CARDS, FREEPOST NAT3271, Edinburgh EH16 4BR
- A free phone number for suspected adverse drug reactions 0800 731 6789

Yellow cards are available in the back of the BNF.

Annual Return of Yellow Fever Vaccine Utilisation and Vaccine Associated Adverse Events

Please insert your Yellow Fever Vaccination Centre stamp in box:

Name of Yellow Fever Vaccination Centre: _____

Utilisation of Yellow Fever Vaccine

Total number of vaccine doses administered:

Vaccine Name: _____

Number of doses: _____

Number (if any) of adverse events reported on the yellow card system:

This form should be returned to HPS annually to arrive by 31st January.

Statistics pertaining to individual clinics will not be published.

The Travel and International Health Team (*Yellow Fever*)
NHS National Services Scotland
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

Fax: 0141 300 1170

Appendix 8

Example Yellow Fever Vaccination Record

Patient Name (Family name, First name)	Patient ID Number	DoB	Date of Vaccination	Vaccine			Name and status of Vaccinator	Destination Country	Remarks/special instructions
				Trade name	Batch number	Expiry date			



DE-DESIGNATION OF YELLOW FEVER VACCINATION CENTRES

July 2011

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1. Introduction

1.1 The International Health Regulations (IHRs) on Yellow Fever vaccinations assist in preventing the international spread of Yellow Fever.

1.2 Under the IHRs, Yellow Fever can only be administered at Yellow Fever Vaccination Centres (YFVCs) that are designated by a State Party's national health administrative system (as defined by the IHR).

1.3 In order to gain designated status, YFVCs need to both achieve and thereafter maintain certain standards to allow them to administer the Yellow Fever vaccine. It is the remit of each State Party's national health administrative system to regulate the practices and procedures of the YFVCs in order to ensure "the quality and safety of the procedures and materials employed."¹

1.4 In Scotland, the Scottish Government is the national health administrative system tasked with the designation responsibility.

1.5 In accordance with its powers the Scottish Government has delegated the responsibility for designation and administration of YFVCs to Health Protection Scotland (HPS). The legislative authority for HPS to do this on behalf of the Scottish Government falls under section 10 of the National Health Service (Scotland) Act 1978 and specifically the National Health Service (Functions of the Common Services Agency (Scotland) Amendment (No.2) Order 2006 SS1/206/603.²

1.6 As a consequence, HPS has produced the information pack "Designation of Yellow Fever Vaccination Centres" that provides, amongst other things, details of the standards that have to be met in order for centres to become, and thereafter maintain their status as designated YFVCs.

1.7 HPS continually monitors YFVC's compliance with the standards through, amongst other things, an ongoing YFVC review programme.

1.8 As well as designating YFVCs, HPS also has the power to de-designate those YFVCs who fail to maintain the required standards.

1.9 Such de-designation will take place in accordance with the de-designation processes contained herein.

¹ Revision of International Health Regulations. WHA 58.3. Fifty-eighth World Health Assembly. 23 May 2005. Annex 6 and 7. Also see Chapter 1 Arrival and Departure. Available at <http://www.who.int/csr/ihr/en/>

² National Health Service Amendment Order
http://www.oqps.gov.uk/legislation/ssi/ssi2006/ssi_20060603_en_1

2. De-designating a YFVC

2.1 HPS will de-designate an existing YFVC if at any time, whether through the ongoing inspection process or otherwise, it comes to their attention that a YFVC is in breach of, or otherwise failing to maintain, the standards of practice required in accordance with the parts 2 – 11 of the “Designation of YFVCs – Information pack”.

2.2 For the avoidance of doubt each YFVC is required to maintain the following standards in order to remain as a designated centre:–

2.2.1 The requirement to issue an International Certificate of Vaccination or Prophylaxis in accordance with paragraphs 2.2 – 2.4 of the Information pack.

2.2.2 The “Conditions of Designation” laid down in paragraph 3.1 of the information pack.

2.2.3 The requirement to be familiar with the Summary of Product Characteristics of the live attenuated vaccine in accordance with paragraph 4 of the information pack.

2.2.4 The requirements for record keeping laid down in Part 5 of the information pack.

2.2.5 The requirements with regard to storage of the yellow fever vaccine as laid out in Part 6 of the information pack.

2.2.6 The requirements for disposal of the yellow fever vaccine in accordance with Part 7 of the information pack.

2.2.7 The requirements for dealing with the yellow fever vaccine should the cold chain be interrupted as laid down in Part 8 of the information pack.

2.2.8 The requirement that all healthcare professionals with responsibility for immunisation should be familiar with techniques for the management of anaphylaxis as laid down in Part 9 of the information pack.

2.2.9 The standards outlined in the Conditions of Registration found at Appendix 1a to the information pack.

2.2.10 Any designated YFVC who fails to maintain the standards laid out in the information pack and part 2.2 herein will become subject to the de-designation process described in part 3 herein.

3. The de-designation process

3.1 For the purposes of the de-designation process breaches of the standards with regard to the attendance at training will be dealt with separately to breaches of the other standards contained in the information pack.

3.2 Breaches of the standards for designation in parts 2 – 11 of the Information pack other save for those breaches relating to the failure to attend mandatory training

3.2.1 Should it come to the attention of HPS, either through the ongoing review process or otherwise, that a designated YFVC is in breach or otherwise failing to maintain any of the standards dealt with by this paragraph 3.2, then the following de-designation process will be followed:

3.2.1.1 Should the breach become apparent as part of the ongoing review process, then the designated YFVC involved will receive notification from HPS of whatever standard/s has been breached together with notification that the YFVC has been categorised as “under review” and will be subject to a further, more detailed, record and/or YFVC review (Appendix 1).

3.2.1.2 Should HPS become aware that a designated YFVC is in breach or otherwise failing to maintain one of the standards for designation in circumstances outside of the ongoing review process, then the designated YFVC involved will receive notification from HPS of whatever standard/s has been breached together with notification that the YFVC has been categorised as “under review” such that it will be subject to a detailed record and/or YFVC review (Appendix 2).

3.2.1.3 In circumstances where, in the judgement of HPS, the breach/es committed by a YFVC in paragraphs 3.2.1.1 and 3.2.1.2 are so serious as to put the YFVC’s ability to administer Yellow Fever vaccinations safely in doubt, HPS has an unfettered discretion to suspend the YFVC involved from administering any further vaccinations whilst the breaches are investigated (Appendix 3).

3.2.1.4 Should it come to the attention of HPS that further breaches of the standards for designation have been committed by any designated YFVC categorised as “under review”, then that YFVC will be suspended from being able to administer any further vaccines whilst the suspected breaches are investigated by HPS (Appendix 4).

3.2.1.5 Should it become apparent following the detailed review that the designated YFVC in question is complying with the standards for designation, then the “under review” categorisation will be lifted and the YFVC able to continue to administer yellow fever vaccinations as normal (Appendix 5).

3.2.1.6 Should HPS judge, during the review process, that the breaches committed by the designated YFVC render it unsafe for them to continue to administer yellow fever vaccines, then HPS has an unfettered discretion to suspend the YFVC involved from administering any further vaccines whilst the breaches are remedied and the standards met in accordance with paragraph 3.2.1.7 – 3.2.1.10 herein (Appendix 6).

3.2.1.7 Following the detailed review/further review, should the breaches be proven to be being committed by the designated YFVC categorised as “under review”, then a remedial time limited action plan will be agreed between HPS and the YFVC in order that the breaches be remedied (Appendix 7).

3.2.1.8 Following expiration of the time limit allowed in accordance with paragraph 3.2.1.7 herein, the designated YFVC categorised as “under review” will be subject to a further record and/or YFVC review (Appendix 7).

3.2.1.9 Should it become apparent during the further review that the breaches have not been remedied in accordance with the action plan then HPS will withdraw the designated status of the YFVC such that they will no longer be entitled to administer yellow fever vaccinations (Appendix 8).

3.2.1.10 Should the breaches have been remedied then the “under review” categorisation will be removed and/or the suspension lifted and the YFVC will be entitled to continue to administer yellow fever vaccinations as normal (Appendix 5).

3.3 Failure to attend mandatory training

3.3.1 Should a designated YFVC fail to abide by the training requirements laid down in the standards for designation, then the following de-designation process will be followed:-

3.3.1.1 The designated YFVC will be notified that they are in breach of the relevant standard for designation, i.e. the standard relating to training. The YFVC will be given a specified period in which to remedy the breach. Should action be taken to remedy the breach in the time period specified, then the designated centre will be entitled to continue to administer yellow fever vaccinations as normal (Appendix 9).

3.3.1.2 Should there be a failure to remedy the breach within the specified time period then the designated YFVC will be given notice that they have a further period to remedy the breach during which they will be suspended from being able to administer further yellow fever vaccinations. Should action be taken to remedy the breach in the further time period specified then the designated centre will be entitled to continue to administer yellow fever vaccinations as normal (Appendix 10).

3.3.1.3 Should there be a failure to remedy the breach within the further time period, then HPS will withdraw the designated status of the offending YFVC such that they will no longer be able to administer yellow fever vaccinations (Appendix 11).

4. Repeated breaches of the standards for designation

4.1 Should a centre commit repeated breaches of the standards for designation then HPS has discretion to withdraw their designated status notwithstanding the fact that such breaches may repeatedly be rectified

5. Applications for designation following de-designation

5.1 Centres that are de-designated will be entitled to apply to become designated centres again should they feel able to comply with the standards for designation in the future.

5.2 Any de-designated centres reapplying for designated status will be subject to a review by HPS as part of the application process to ensure compliance with the standards.

5.3 HPS has an unfettered discretion as to whether or not it is prepared to allow a formerly de-designated centre to become a designated centre again in the future.

6. Disputes and appeals against de-designation

6.1 Should a designated YFVC feel that they have complied with and met all the conditions of designation, as laid down by HPS, paragraph 3.1 of the information pack. The designated YFVC has the right to dispute and appeal against the decision of HPS to de-designate the YFVC.

6.2 In the event of a dispute or appeal against being de-designated the YFVC must in the first instance address their complaint to:

Yellow Fever Vaccination Centre Co-ordinator
The Travel and International Health Team (*Yellow Fever*)
NHS National Services Scotland
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

6.3 In the event of a complaint made by a designated YFVC not being dealt with fairly by HPS, in the opinion of the designated YFVC then the centre has the right to appeal or to take their complaint to the Director, and should be addressed to:

The Director
NHS National Services Scotland
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

6.4 Arbitration

In the event that the designated YFVC feels their complaint or appeal against HPS has not been dealt with fairly, then the designated YFVC may appeal to the Chief Executive of National Services Scotland, and should be addressed to:

The Chief Executive
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Whose decision in all matters will be final.

Acknowledgement

This document sets out the conditions of de-designation for Yellow Fever Vaccination Centres (YFVCs) in Scotland. It has been adapted, with permission, from an original document formulated by the National Travel Health Network and Centre (NaTHNaC), to be specific for YFVCs in Scotland. Our thanks to Professor David Hill and the staff at NaTHNaC for allowing us to utilise their materials..

Any queries regarding the de-designation process should be directed in the first instance to:-

The Travel and International Health Team (*Yellow Fever*)
NHS National Services Scotland
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE

www.hps.scot.nhs.uk

Telephone: 0141 300 1948

e-mail: nss.hpsyellowfever@nhs.net